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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,097	03/15/2004	Gustavo Antonio Moviglia	545872000100	4725
20872 7590 06/12/2007 MORRISON & FOERSTER LLP 425 MARKET STREET SAN FRANCISCO, CA 94105-2482			EXAMINER QIAN, CELINE X	
			ART UNIT 1636	PAPER NUMBER
			MAIL DATE 06/12/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/802,097

Applicant(s)

MOVIGLIA, GUSTAVO ANTONIO

Examiner

Celine X. Qian Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-77 is/are pending in the application.
- 4a) Of the above claim(s) 1-9 and 24-77 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>0304,0805</u> .   | 6) <input type="checkbox"/> Other: ____.                          |

### **DETAILED ACTION**

Claims 1-77 are pending in the application.

#### ***Election/Restrictions***

Applicant's election with traverse of Group II in the reply filed on 3/28/07 is acknowledged. The traversal is on the ground(s) that each of the groups of claims includes tumor B-cell hybrid cells, so that the search of all groups will not be burdensome.

This is not found persuasive because the invention of each group is patentably distinct from each other for reasons set forth in the previous office action. Although the invention of Groups I-III all recite tumor B-cell hybrid cells, each invention also comprises additional elements which made the invention distinct from each other. A search of the invention of one group is not co-extensive with the search of another group. Therefore, a search of the invention of Groups I-III would have been burdensome. The invention of Groups IV-VII does not recite tumor B-cell hybrid cells. Therefore, they are distinct from the invention of Groups I-III because they do not require the composition of Groups I-III to practice the claimed method. A search of inventions I-VII would have been burdensome because the search of each group is not co-extensive.

The requirement is still deemed proper and is therefore made FINAL.

Accordingly, claims 1-9, 24-77 are withdrawn from consideration for being directed to non-elected subject matter. Claims 10-23 are currently under examination.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guo et al. (IDS, 1994), in view of Movglia (1996, IDS).

Guo et al. teach fusion of BERH-2 rat hepatocellular carcinoma cells with activated B cells produced hybrid cells (TBH) that lost their tumorigenicity and became immunogenic (see abstract, and page 516-517, and Figure 2). Guo et al. also teach that the TBH injection eradicated established hepatomas, and also prolong the survival of those rats (see page 517, 1<sup>st</sup> col., through 2<sup>nd</sup> col). Guo et al. further teach that CD8+ cells can mediate tumor cell destruction in the absence of CD4+ cells, and such action is tumor specific (see page 517, 2<sup>nd</sup> col., and Table 1, and page 518, 1<sup>st</sup> paragraph). Lastly, Guo et al. teach that the discovery of tumor/B cell hybrid can stimulate tumor immunity has broad clinical application and may provide a useful strategy for cancer immunotherapy. However, Guo et al. does not teach a composition comprises a plurality of cells including isolated human CD 8+ cells and tumor/B-cell hybrid cells.

Movglia teaches that patients injected to TBH show that TBH auto-vaccination has a positive therapeutic effect on different human tumors, with low overall toxicity. Movglia also teaches that the activated B-cell is one of the best APCs for both CD4 and CD8 cells because the lymphocyte is able to express not only MHC II molecules on its membrane, but every other necessary co-stimulating compound as well. Through hybridization procedure, these B-cell

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properties are transmitted to the tumor cells (see page 647, last paragraph of 1<sup>st</sup> col., through 1<sup>st</sup> col., of 2<sup>nd</sup> col). Movgia indicate that the antitumor effect of TBH in the induction period needs both CD4 and CD8, provided that their number is sufficient, and their competence normal, whereas the progression and maintenance stage, only CD8 is necessary.

It would have been obvious to one of ordinary skill in the art to make a composition comprising isolated CD8+ cells and TBH from the same individual based on the combined teaching of Guo et al. and Movgia. One of ordinary skill in the art would be motivated to do so because the observation of CD8+ cells activated by TBH is required for TBH antitumor therapeutic activity. The ordinary artisan would want to have more activated CD8+ cells available for the killing of tumor cells in the host, especially when the host does not have sufficient competent CD8+ cells. The level of skill in the art is high. Absent evidence from the contrary, one of ordinary skill in the art would have reasonable expectation of success to activate CD8+ cells *in vitro* or *in vivo* by TBH. Therefore, the claimed invention would have been *prima facie* obvious at the time the invention was made.

Claims 18-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guo et al. (IDS, 1994), in view of Movglia (1996, IDS) and Gong et al (WO 01/59073).

The teaching of Guo and Movglia were discussed above. However, Guo and Movglia do not teach a method of generating CD8+ cells contacted with tumor/B-cell hybrid cells by contacting isolated CD8+ cells with tumor/B-cell hybrid cells for a sufficient time to stimulate proliferation of CD8+ cells that recognize tumor antigens.

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Gong et al. teach method of activating T cells by contacting CD8+ T cells with tumor antigen fusion cells in vitro or in vivo (see for example, page 13, lines 10-32, and page 25, lines 23-29, and page 27, 2<sup>nd</sup>-3<sup>rd</sup> paragraph).

The obviousness of generating a composition comprising isolated CD8+ cells with TBH or activated CD8+ cells were discussed above. The method of generating said CD8+ is well documented in the prior art as evidenced by Gong et al. Gong et al. teaches a method of generating activated CD8+ cells by contacting said cells with the antigen either in vivo or in vitro. Absent evidence to the contrary, one of ordinary skill in the art would have reasonable expectation of success to activate CD8+ cells as claimed. To test whether such cells can achieve antitumor effect in vivo, it would have been obvious to inject said cells into an individual. Therefore, the claimed invention would have been *prima facie* obvious at the time the invention was made.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X. Qian Ph.D. whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Woitach Ph.D. can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Celine X Qian Ph.D.  
Examiner  
Art Unit 1636

CELINE QIAN, PH.D.  
PRIMARY EXAMINER

